• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–3361 for ''Eligibility Criteria for Expanded Conditional Approval of New Animal Drugs.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Christopher Loss, Center for Veterinary Medicine (HFV–116), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0619, *christopher.loss@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of draft GFI #261 entitled ''Eligibility Criteria for Expanded Conditional Approval of New Animal Drugs.'' In 2013, in conjunction with the reauthorization of FDA's animal drug user fee program, FDA agreed to consider whether it would be appropriate to expand the concept of conditional approval in section 571 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360ccc) to include new animal drug use in major species for diseases or conditions that would not be eligible for conditional approval under the MUMS provisions of the FD&C Act. Through a public process and working in concert with stakeholders, CVM explored the feasibility of expanding the eligibility for conditional approval. CVM concluded that conditional approval may be appropriate for new animal drugs intended for a serious or life-threatening disease or condition, or for drugs intended to address an unmet animal or human health need under circumstances where a demonstration of effectiveness would require a particularly difficult effectiveness study or studies. The Animal Drug User Fee Amendments of 2018 amended section 571 of the FD&C Act to include provisions for expanded conditional approval and directed FDA to establish guidance or regulations to clarify the eligibility criteria for expanded conditional approval.

In accordance with the recent amendments to the FD&C Act, this draft guidance proposes definitions for the following terms that appear in section 571 of the FD&C Act:

• ''serious or life-threatening disease or condition''

• ''unmet animal or human health need,'' and

• ''complex or particularly difficult study or studies.''

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Eligibility Criteria for Expanded Conditional Approval of New Animal Drugs.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations for new animal drug applications submitted under sections 512(b) (21 U.S.C. 360b(b)) and 571 of the FD&C Act. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 514.1, 514.4, 514.5, 514.6, 514.8, and 514.11 have been approved under OMB control number 0910–0032.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *https://www.regulations.gov.*

Dated: September 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–21002 Filed 9–26–19; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3764]

Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products and Type A Medicated Articles Manufactured From Active Pharmaceutical Ingredients Considered To Be Soluble in Aqueous Media; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is

announcing the availability of a draft guidance for industry (GFI) #171 entitled ''Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products and Type A Medicated Articles Manufactured from Active Pharmaceutical Ingredients Considered to be Soluble in Aqueous Media.'' This draft guidance describes how the Agency intends to evaluate requests for waiving the requirement for performing in vivo bioequivalence studies for animal drugs administered orally as soluble powders or as Type A medicated articles manufactured from active pharmaceutical ingredients considered to be soluble in aqueous media.

DATES: Submit either electronic or written comments on the draft guidance by November 29, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–3764 for ''Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products and Type A Medicated Articles Manufactured from Active Pharmaceutical Ingredients Considered to be Soluble in Aqueous Media.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

- *Biopharmaceutics and Pharmacokinetics:* Marilyn Martinez, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0635, *Marilyn.Martinez@fda.hhs.gov.*
- *Manufacturing Chemistry/Solubility Concerns:* Catherine Finnegan, Center for Veterinary Medicine (HFV–147), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0650, *Catherine.Finnegan@fda.hhs.gov.*
- *Generic Drug Approval Requirements:* Ian S. Hendricks, Center for Veterinary Medicine (HFV–172), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0853, *Ian.Hendricks@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft GFI #171 entitled ''Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products and Type A Medicated Articles Manufactured from Active Pharmaceutical Ingredients Considered to be Soluble in Aqueous Media.'' This draft guidance describes how the Agency intends to evaluate requests for waiving the requirement for performing in vivo bioequivalence studies (biowaivers) for animal drugs administered orally as soluble powders or as Type A medicated articles manufactured from active pharmaceutical ingredients (APIs) considered to be soluble in aqueous media (water soluble APIs). This draft guidance expands upon GFI #35, ''Bioequivalence Guidance,'' published November 8, 2006, to include biowaivers for soluble powder oral dosage form products as well as Type A medicated articles manufactured from active pharmaceutical ingredients considered to be soluble in aqueous media. This draft guidance offers particular focus on criteria for the waiver of the requirements for

submitting in vivo bioequivalence study data.

This draft guidance is applicable to generic investigational new animal drug (JINAD) files and to abbreviated new animal drug applications (ANADAs). Although the recommendations in this guidance refer to generic drug applications, the general principles described may also be applicable to new animal drug applications (NADAs), investigational new animal drug (INAD) files, and supplemental NADAs. This draft guidance does not address Type A medicated articles manufactured from active pharmaceutical ingredients considered to be insoluble in aqueous media.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products and Type A Medicated Articles Manufactured from Active Pharmaceutical Ingredients Considered to be Soluble in Aqueous Media.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This draft guidance refers to collections of information associated with biowaiver requests for generic soluble powder oral dosage form products and Type A medicated articles. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information associated with biowaiver requests for generic soluble powder oral dosage form products and Type A medicated articles are being reviewed by OMB under OMB control number 0910–0669 (see 84 FR 16270 at 16271, April 18, 2019).

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *https://www.regulations.gov.*

Dated: September 25, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–21202 Filed 9–27–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–007]

Fee for Using a Material Threat Medical Countermeasure Priority Review Voucher in Fiscal Year 2020

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the fee rate for using a material threat medical countermeasure (MCM) priority review voucher for fiscal year (FY) 2020. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to determine and collect material threat MCM priority review user fees for certain applications for review of human drug products when those applications use a material threat MCM priority review voucher. These vouchers are awarded to the sponsors of material threat MCM applications that meet all the requirements of this program and upon FDA approval of such applications. The amount of the fee for using a material threat MCM priority review voucher is determined each FY based on the difference between the average cost incurred by FDA to review a human drug application designated as priority review in the previous FY, and the average cost incurred in the review of an application that is not subject to priority review in the previous FY. This notice establishes the material threat MCM priority review fee rate for FY 2020 and outlines the payment procedures for such fees.

FOR FURTHER INFORMATION CONTACT: Melissa Hurley, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705–4304, 240–402–4585.

SUPPLEMENTARY INFORMATION:

I. Background

Section 3086 of the Cures Act (Pub. L. 114–255) added section 565A to the FD&C Act (21 U.S.C. 360bbb–4a). In section 565A of the FD&C Act, Congress encouraged development of material threat MCMs by offering additional incentives for obtaining FDA approval of such products. Under section 565A of the FD&C Act, the sponsor of an eligible material threat MCM application (as defined in section 565A(a)(4)) shall receive a priority review voucher upon approval of the material threat MCM application. The recipient of a material threat MCM priority review voucher may either use the voucher for a future human drug application submitted to FDA under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), or transfer (including by sale) the voucher to another party. The voucher may be transferred (including by sale) repeatedly until it ultimately is used for a human drug application submitted to FDA under section 505(b)(1) of the FD&C Act or section 351(a) of the Public Health Service Act. A priority review is a review conducted with a Prescription Drug User Fee Act (PDUFA) goal date of 6 months after the receipt or filing date, depending on the type of application. Information regarding PDUFA goals is available at *https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm511438.pdf*.

The sponsor that uses a material threat MCM priority review voucher is entitled to a priority review of its eligible human drug application, but must pay FDA a material threat MCM priority review user fee in addition to any user fee required by PDUFA for the application. Information regarding the material threat MCM priority review voucher program is available at: *https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm566498.htm*.

This notice establishes the material threat MCM priority review fee rate for FY 2020 at $2,167,116 and outlines FDA's payment procedures for material threat MCM priority review user fees. This rate is effective on October 1, 2019, and will remain in effect through September 30, 2020.

II. Material Threat Medical Countermeasure Priority Review User Fee for FY 2020

FDA interprets section 565A(c)(2) of the FD&C Act as requiring that FDA determine the amount of the material threat MCM priority review user fee each fiscal year based on the difference between the average cost incurred by FDA in the review of a human drug application subject to priority review in the previous fiscal year, and the average cost incurred by FDA in the review of a human drug application that is not